IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	C.A. No. 18-823-VAC-CJB
Plaintiffs,	)	
v.	)	**PUBLIC VERSION**
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

EAGLE PHARMACEUTICALS, INC.'S ANSWER TO COMPLAINT & COUNTERCLAIMS

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Defendant Eagle Pharmaceuticals, Inc. ("Eagle"), by and through its counsel, hereby responds to the claims asserted by Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par") in their Complaint as follows:

PARTIES

1. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized under the laws of the State of New York having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Eagle is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 1 of the Complaint and therefore denies the same.
2. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized under the laws of the State of Delaware having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Eagle is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 2 of the Complaint and therefore denies the same.
3. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.
4. Eagle admits the allegations set forth in Paragraph 4 of the Complaint.

NATURE OF ACTION

5. Eagle states that the allegations set forth in Paragraph 5 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle

admits that Par, through its Complaint, purports to allege infringement of United States Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit") under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, but denies that Eagle has infringed any of the Patents-in-Suit. Eagle otherwise denies the allegations set forth in Paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. Eagle states that the allegations set forth in Paragraph 6 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) for the purposes of the instant case, but only to the extent each Plaintiff has standing to bring the claims set forth in the Complaint.

7. Eagle states that the allegations set forth in Paragraph 7 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle admits that venue is proper in this District for the purposes of the instant case only.

8. Eagle states that the allegations set forth in Paragraph 8 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle admits that this Court has personal jurisdiction over Eagle for the purposes of the instant case only.

THE DRUG APPROVAL PROCESS

9. Eagle states that the allegations set forth in Paragraph 9 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

10. Eagle states that the allegations set forth in Paragraph 10 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

11. Eagle states that the allegations set forth in Paragraph 11 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

12. Eagle states that the allegations set forth in Paragraph 12 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

13. Eagle states that the allegations set forth in Paragraph 13 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

FACTUAL BACKGROUND

The Patents-In-Suit

14. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Pharmaceutical is the owner of the '478 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension," which issued on or around June 28, 2016. The remaining allegations set forth in Paragraph 14 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

15. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Pharmaceutical is the owner of the '526 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension," which issued on or around June 27, 2017. The remaining allegations set forth in Paragraph 15 of the Complaint are legal conclusions to which no

responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

16. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Pharmaceutical is the owner of the '209 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension," which issued on or around August 29, 2017. The remaining allegations set forth in Paragraph 16 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

17. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Pharmaceutical is the owner of the '239 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension," which issued on or around August 29, 2017. The remaining allegations set forth in Paragraph 17 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

18. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Pharmaceutical is the owner of the '785 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension," which issued on or around September 5, 2017. The remaining allegations set forth in Paragraph 18 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

19. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Pharmaceutical is the owner of the '223 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension," which issued on or around April 10, 2018. The remaining

allegations set forth in Paragraph 19 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

20. Eagle states that the allegations set forth in Paragraph 20 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle states that it is without sufficient information to form a belief as to the allegations set forth in Paragraph 20 of the Complaint and therefore denies the same.

VASOSTRICT®

21. Eagle admits that vasopressin is a polypeptide hormone that causes constriction of vascular and other smooth muscle cells and is the active ingredient in VASOSTRICT®. Eagle is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 21 of the Complaint and therefore denies the same.

22. Eagle admits that the FDA first granted approval to NDA No. 204485 on April 17, 2014. Eagle is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 22 of the Complaint and therefore denies the same.

23. Eagle is without sufficient information to form a belief as to the allegations set forth in Paragraph 23 of the Complaint and therefore denies the same.

24. Eagle admits that the FDA granted approval to NDA No. 204485/S-003, regarding the 20 units/mL in 1 mL vial formulation of VASOSTRICT®, on or around March 18, 2016 and to NDA No. 204485/S-004, regarding the 200 units/10 mL in 10 mL vial formulation of VASOSTRICT®, on or around December 17, 2016. Eagle is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 24 of the Complaint and therefore denies the same.

25. Eagle admits upon information and belief, based on the facts alleged in the Complaint, that Par Sterile Products is the holder of NDA No. 204485 and the supplements thereto.

26. Eagle admits that the Patents-in-Suit have been listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") in connection with VASOSTRICT®. The remaining allegations set forth in Paragraph 26 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

27. Eagle admits that VASOSTRICT® is indicated to increase blood pressure in adults with vasodilatory shock (*e.g.*, post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Eagle is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 27 of the Complaint and therefore denies the same.

Eagle's Generic Vasopressin Product

28. Eagle admits the allegations set forth in Paragraph 28 of the Complaint.

29. Eagle admits the allegations set forth in Paragraph 29 of the Complaint.

30. Eagle admits that, by letters dated April 16, 2018 and May 18, 2018, it provided notice to Par Sterile Products and Par Pharmaceutical that ANDA No. 211538 included Paragraph IV certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Eagle's Proposed ANDA Product. Eagle further admits that its April 16, 2018 and May 18, 2018 letters each included an Offer of Confidential Access to Eagle's ANDA No. 211538 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) for the sole and exclusive purpose of determining whether an infringement action under 21 U.S.C. § 355(j)(5)(B)(iii) could be brought with respect to the Patents-in-Suit. Eagle denies any remaining allegations set forth in Paragraph 30 of the Complaint.

31. Eagle admits that Par requested access to Eagle's ANDA No. 211538 pursuant to the terms of Eagle's Offer of Confidential Access on May 14, 2018 by providing Eagle with an executed copy of Eagle's Offer of Confidential Access. Eagle admits that pursuant to the terms of its Offer of Confidential Access, Eagle produced ANDA No. 211538 "redacted to remove portions of no relevance to any issue of patent infringement" in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III). Eagle denies any remaining allegations set forth in Paragraph 31 of the Complaint.

32. Eagle admits that Par requested access to the redacted portions of Eagle's ANDA No. 211538 and that Par alleged that it was otherwise unable to conduct a full and complete infringement analysis of Eagle's ANDA. Eagle denies that Par was unable to conduct a full and complete infringement analysis with respect to the Patents-in-Suit based on Eagle's ANDA production under the Offer of Confidential Access, and denies any remaining allegations set forth in Paragraph 32 of the Complaint.

33. Eagle admits that Par requested access to the redacted portions of Eagle's ANDA No. 211538 and that Par alleged that it was otherwise unable to conduct a full and complete infringement analysis of Eagle's ANDA. Eagle denies that Par was unable to conduct a full and complete infringement analysis with respect to the Patents-in-Suit based on Eagle's ANDA production under the Offer of Confidential Access, and denies any remaining allegations set forth in Paragraph 33 of the Complaint.

34. Eagle admits that pursuant to the terms of its Offer of Confidential Access, Eagle produced ANDA No. 211538 "redacted to remove portions of no relevance to any issue of patent infringement" in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III), and that it has not made any additional production of ANDA No. 211538 outside of the terms of Eagle's Offer of

Confidential Access. Eagle denies the remaining allegations set forth in Paragraph 34 of the Complaint.

35. Eagle denies the allegations set forth in Paragraph 35 of the Complaint.

36. Eagle is without sufficient information to form a belief as to the allegations set forth in Paragraph 36 of the Complaint and therefore denies the same.

37. Eagle states that the allegations set forth in Paragraph 37 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

COUNT I:
INFRINGEMENT OF THE '239 PATENT

38. Eagle incorporates by reference and realleges its responses to the allegations set forth in Paragraphs 1–37 of the Complaint.

39. Eagle states that the allegations set forth in Paragraph 39 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

40. Eagle states that the allegations set forth in Paragraph 40 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

41. Eagle admits that claim 1 of the '239 patent recites as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration consisting of, in a unit dosage form: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) optionally chlorobutanol; iii) acetic acid, acetate, or a combination thereof; iv) 0-2% vasopressin degradation products; and v) water;

b) diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and

c) administering the diluted unit dosage form to the human by intravenous administration; wherein:

the unit dosage form has a pH of 3.5 to 4.1; the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
the human is hypotensive.

Eagle states that the remaining allegations set forth in Paragraph 41 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

42. Eagle states that the allegations set forth in Paragraph 42 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

43. Eagle states that the allegations set forth in Paragraph 43 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

44. Eagle admits that it was aware of the existence of the '239 patent when it submitted ANDA No. 211538. Eagle states that the remaining allegations set forth in Paragraph 44 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

45. Eagle states that the allegations set forth in Paragraph 45 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

COUNT II:
INFRINGEMENT OF THE '223 PATENT

46. Eagle incorporates by reference and realleges its responses to the allegations set forth in Paragraphs 1–45 of the Complaint.

47. Eagle states that the allegations set forth in Paragraph 47 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

48. Eagle states that the allegations set forth in Paragraph 48 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

49. Eagle states that the allegations set forth in Paragraph 49 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

50. Eagle admits that claim 1 of the '223 patent recites as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration comprising: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; ii) acetate buffer; and iii) water, wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8,
>
> wherein the pharmaceutical composition is provided in a container;
>
> b) puncturing a dispensing region of the container a first time and drawing from the container a portion of the pharmaceutical composition;
>
> c) intravenously administering the portion of the pharmaceutical composition to the human,
>
> wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically acceptable salt thereof per minute,
>
> wherein the human is hypotensive;
>
> d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition, wherein

the second time that the dispensing region of the container is punctured occurs at least 48hours after the first time that the dispensing region of the container is punctured;

e) intravenously administering the second portion of the pharmaceutical composition to the human,

wherein the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically acceptable salt thereof per minute.

Eagle states that the remaining allegations set forth in Paragraph 50 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

51. Eagle states that the allegations set forth in Paragraph 51 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

52. Eagle admits that it was aware of the existence of the '223 patent when it submitted its Paragraph IV certification with respect to the '223 patent in connection with ANDA No. 211538. Eagle states that the remaining allegations set forth in Paragraph 52 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

53. Eagle states that the allegations set forth in Paragraph 53 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

COUNT III:
INFRINGEMENT OF THE '478 PATENT

54. Eagle incorporates by reference and realleges its responses to the allegations set forth in Paragraphs 1–53 of the Complaint.

55. Eagle states that the allegations set forth in Paragraph 55 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

56. Eagle states that the allegations set forth in Paragraph 56 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

57. Eagle admits that claim 1 of the '478 patent recites as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form consists essentially of:
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> a) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
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> b) 10 mM acetate buffer; and
>
> c) water,
>
> wherein:
>
> the unit dosage form has a pH of 3.8; the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

Eagle states that the remaining allegations set forth in Paragraph 57 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

58. Eagle states that the allegations set forth in Paragraph 58 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

59. Eagle states that the allegations set forth in Paragraph 59 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

60. Eagle admits that it was aware of the existence of the '478 patent when it submitted ANDA No. 211538. Eagle states that the remaining allegations set forth in Paragraph 60 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

61. Eagle states that the allegations set forth in Paragraph 61 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

COUNT IV:
INFRINGEMENT OF THE '526 PATENT

62. Eagle incorporates by reference and realleges its responses to the allegations set forth in Paragraphs 1–61 of the Complaint.

63. Eagle states that the allegations set forth in Paragraph 63 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

64. Eagle states that the allegations set forth in Paragraph 64 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

65. Eagle admits that claim 1 of the '526 patent recites as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration comprising: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) acetic acid; and iii) water,

wherein the pharmaceutical composition has a pH of 3.8; b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and

c) intravenously administering the pharmaceutical composition to the human,

wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,

wherein the human is hypotensive,

wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

Eagle states that the remaining allegations set forth in Paragraph 65 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

66. Eagle states that the allegations set forth in Paragraph 66 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

67. Eagle states that the allegations set forth in Paragraph 67 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

68. Eagle admits that it was aware of the '526 patent when it submitted ANDA No. 211538. Eagle states that the remaining allegations set forth in Paragraph 68 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

69. Eagle states that the allegations set forth in Paragraph 69 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

COUNT V:
INFRINGEMENT OF THE '785 PATENT

70. Eagle incorporates by reference and realleges its responses to the allegations set forth in Paragraphs 1–69 of the Complaint.

71. Eagle states that the allegations set forth in Paragraph 71 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

72. Eagle states that the allegations set forth in Paragraph 72 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

73. Eagle admits that claim 1 of the '785 patent recites as follows:

> A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

Eagle states that the remaining allegations set forth in Paragraph 73 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

74. Eagle states that the allegations set forth in Paragraph 74 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

75. Eagle states that the allegations set forth in Paragraph 75 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

76. Eagle admits that it was aware of the '785 patent when it submitted ANDA No. 211538. Eagle states that the remaining allegations set forth in Paragraph 76 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

77. Eagle states that the allegations set forth in Paragraph 77 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

COUNT VI:
INFRINGEMENT OF THE '209 PATENT

78. Eagle incorporates by reference and realleges its responses to the allegations set forth in Paragraphs 1–77 of the Complaint.

79. Eagle states that the allegations set forth in Paragraph 79 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

80. Eagle states that the allegations set forth in Paragraph 80 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

81. Eagle admits that claim 1 of the '209 patent recites as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof,
>
> wherein:
>
> the unit dosage form has a pH of 3.7-3.9;
>
> the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and

the human is hypotensive.

Eagle states that the remaining allegations set forth in Paragraph 81 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

82. Eagle states that the allegations set forth in Paragraph 82 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

83. Eagle states that the allegations set forth in Paragraph 83 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

84. Eagle admits that it was aware of the '209 patent when it submitted ANDA No. 211538. Eagle states that the remaining allegations set forth in Paragraph 84 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

85. Eagle state`s that the allegations set forth in Paragraph 85 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Eagle denies the same.

PRAYER FOR RELIEF

The remainder of the Complaint is a Prayer for Relief, as to which no response is necessary. To the extent any response is required, Eagle denies that Par is entitled to any remedy or relief.

DEFENSES

Eagle hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Eagle reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST DEFENSE

The claims of the Patents-in-Suit are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including Sections 101, 102, 103, or 112, or other judicially created bases for invalidation, such as double patenting. For example, without limitation, the Patents-in-Suit are invalid for the reasons set forth in the Detailed Statement of the Factual And Legal Bases For Eagle Pharmaceutical Eagle Pharmaceuticals, Inc.'s Certification That U.S. Patent Nos. 9,375,478, 9,687,526, 9,744,209, 9,744,239, and 9,750,785 Are Invalid, Unenforceable, And/Or Will Not Be Infringed By The Manufacture, Use, Sale, Offer For Sale, Or Importation Of Eagle's Vasopressin Product As Defined By ANDA No. 211538, and the Detailed Statement of the Factual And Legal Bases For Eagle Pharmaceutical Eagle Pharmaceuticals, Inc.'s Certification That U.S. Patent No. 9,937,223 Is Invalid, Unenforceable, And/Or Will Not Be Infringed By The Manufacture, Use, Sale, Offer For Sale, Or Importation Of Eagle's Vasopressin Product As Defined By ANDA No. 211538, which were served by Eagle on Par Sterile Products and Par Pharmaceutical on April 16, 2018 and May 18, 2018, respectively.

SECOND DEFENSE

The submission of Eagle's ANDA No. 211538 has not infringed and does not infringe any valid and enforceable claim of the Patents-in-Suit either directly or indirectly, and either literally or under the doctrine of equivalents. For example, without limitation, the submission of Eagle's ANDA No. 211538 has not infringed and does not infringe any valid and enforceable claim of the Patents-in-Suit for the reasons set forth in the Detailed Statement of the Factual And Legal Bases

For Eagle Pharmaceutical Eagle Pharmaceuticals, Inc.'s Certification That U.S. Patent Nos. 9,375,478, 9,687,526, 9,744,209, 9,744,239, and 9,750,785 Are Invalid, Unenforceable, And/Or Will Not Be Infringed By The Manufacture, Use, Sale, Offer For Sale, Or Importation Of Eagle's Vasopressin Product As Defined By ANDA No. 211538, and the Detailed Statement of the Factual And Legal Bases For Eagle Pharmaceutical Eagle Pharmaceuticals, Inc.'s Certification That U.S. Patent No. 9,937,223 Is Invalid, Unenforceable, And/Or Will Not Be Infringed By The Manufacture, Use, Sale, Offer For Sale, Or Importation Of Eagle's Vasopressin Product As Defined By ANDA No. 211538, which were served by Eagle on Par Sterile Products and Par Pharmaceutical on April 16, 2018 and May 18, 2018, respectively.

THIRD DEFENSE

The manufacture, use, sale, offer for sale, or importation of Eagle's Proposed ANDA Product has not infringed, does not infringe, and would not infringe any valid claim of the Patents-in-Suit either directly or indirectly, and either literally or under the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of Eagle's Proposed ANDA Product has not infringed, does not infringe, and would not infringe any valid claim of the Patents-in-Suit for the reasons set forth in the Detailed Statement of the Factual And Legal Bases For Eagle Pharmaceutical Eagle Pharmaceuticals, Inc.'s Certification That U.S. Patent Nos. 9,375,478, 9,687,526, 9,744,209, 9,744,239, and 9,750,785 Are Invalid, Unenforceable, And/Or Will Not Be Infringed By The Manufacture, Use, Sale, Offer For Sale, Or Importation Of Eagle's Vasopressin Product As Defined By ANDA No. 211538, and the Detailed Statement of the Factual And Legal Bases For Eagle Pharmaceutical Eagle Pharmaceuticals, Inc.'s Certification That U.S. Patent No. 9,937,223 Is Invalid, Unenforceable, And/Or Will Not Be Infringed By The Manufacture, Use, Sale, Offer For Sale, Or Importation Of Eagle's Vasopressin Product As

Defined By ANDA No. 211538, which were served by Eagle on Par Sterile Products and Par Pharmaceutical on April 16, 2018 and May 18, 2018, respectively.

FOURTH DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

FIFTH DEFENSE

Eagle's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SIXTH DEFENSE

One or more Plaintiffs lack standing to bring and maintain this lawsuit against Eagle.

SEVENTH DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs/Counterclaim Defendants Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par"), Defendant/Counterclaim Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle") states as follows:

NATURE OF THE ACTION

1. Eagle seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that the claims of United States Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit") are invalid, and have not been infringed, are not being infringed, and will not be infringed by the submission of Eagle's ANDA No. 211538 or the manufacture, use, sale, offer for sale, or importation of Eagle's Proposed ANDA Product.

THE PARTIES

2. Defendant/Counterclaim Plaintiff Eagle is a corporation organized under the laws of the State of Delaware having a principal place of business at 50 Tice Road, Suite 315, Woodcliff, New Jersey, 07677.

3. Upon information and belief, based on the facts alleged in Par's Complaint, Plaintiff/Counterclaim Defendant Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, based on the facts alleged in Par's Complaint, Plaintiff/Counterclaim Defendant Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

5. Upon information and belief, based on the facts alleged in Par's Complaint, Plaintiff/Counterclaim Defendant Endo Par Innovation Company ("EPIC") is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

JURISDICTION & VENUE

6. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. Par has filed a Complaint in this District alleging infringement by Eagle of one or more claims of each of the Patents-in-Suit. An actual controversy exists between Eagle and Par as to the alleged infringement and validity of the Patents-in-Suit.

8. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

9. This Court has personal jurisdiction over Par Pharmaceutical because, inter alia, Par Pharmaceutical has subjected itself to the jurisdiction of this Court by filing its Complaint.

10. This Court has personal jurisdiction over Par Sterile Products because, inter alia, Par Sterile Products is a corporation organized under the laws of the State of Delaware and has subjected itself to the jurisdiction of this Court by filing its Complaint.

11. This Court has personal jurisdiction over EPIC because, inter alia, EPIC is a corporation organized under the laws of the State of Delaware and has subjected itself to the jurisdiction of this Court by filing its Complaint.

BACKGROUND

12. Upon information and belief, on or around August 26, 2016, the United States Patent & Trademark Office ("USPTO") issued the '478 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension." Upon information and belief, Par Pharmaceutical owns the '478 patent.

13. Upon information and belief, on or around June 27, 2017, the USPTO issued the '526 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension." Upon information and belief, Par Pharmaceutical owns the '526 patent.

14. Upon information and belief, on or around August 29, 2017, the USPTO issued the '209 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension." Upon information and belief, Par Pharmaceutical owns the '209 patent.

15. Upon information and belief, on or around August 29, 2017, the USPTO issued the '239 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension." Upon information and belief, Par Pharmaceutical owns the '239 patent.

16. Upon information and belief, on or around September 5, 2017, the USPTO issued the '785 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension." Upon information and belief, Par Pharmaceutical owns the '785 patent.

17. Upon information and belief, on or around April 10, 2018, the USPTO issued the '223 patent, titled "Vasopressin Formulations For Use In Treatment of Hypotension." Upon information and belief, Par Pharmaceutical owns the '223 patent.

18. By letter dated April 16, 2018 ("First Notice Letter") and in accordance with 21 U.S.C. § 355(j)(2)(B), Eagle provided notice to Par Sterile Products and Par Pharmaceutical that Eagle had submitted ANDA No. 211538 seeking approval for Eagle's Proposed ANDA Product and that ANDA No. 211538 included Paragraph IV certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '478, '526, '209, '239, and '785 patents are invalid, unenforceable, and/or will not be infringed by Eagle's Proposed ANDA Product.

19. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(ii), the First Notice Letter included a detailed statement of the factual and legal bases for the certifications that the '478, '526, '209, '239, and '785 patents are invalid, unenforceable, and/or will not be infringed by Eagle's Proposed ANDA Product.

20. By letter dated May 15, 2018 ("Second Notice Letter") and in accordance with 21 U.S.C. § 355(j)(2)(B), Eagle provided notice to Par Sterile Products and Par Pharmaceutical that Eagle had submitted ANDA No. 211538 seeking approval for Eagle's Proposed ANDA Product and that ANDA No. 211538 included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '223 patent is invalid, unenforceable, and/or will not be infringed by Eagle's Proposed ANDA Product.

21. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(ii), the Second Notice Letter included a detailed statement of the factual and legal bases for the certification that the '223 patent is invalid, unenforceable, and/or will not be infringed by Eagle's Proposed ANDA Product.

22. On May 31, 2018, Par initiated this action against Eagle alleging infringement of the Patents-in-Suit.

FIRST COUNTERCLAIM
Noninfringement of the '478 Patent

23. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–22 of its Counterclaims as if fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the noninfringement of the '478 Patent.

25. Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '478 patent. By way of non-limiting example, as set forth in the First Notice Letter, [redacted] and therefore does not infringe any claim of the '478 patent.

26. In addition, the claims of the '478 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, each alone or in combination with one or more others, including: T. Treschan & J. Peters, *The Vasopressin System, Physiology and Clinical Studies*, 105 Anesthesiology 599

(2006) ("Treschan"); Pharm. Partners Can., *Vasopressin Injection, USP* (2009) ("PPC"); Fresenius Kabi USA, LLC, NovaPlus® (2014) ("Fresenius Label"); JHP Pharm., *Pitressin*® (2012) ("Pitressin Label"); M. Argenziano, *A Prospective Randomized Trial of Arginine Vasopressin in the Treatment of Vasodilatory Shock After Left Ventricular Assist Device Placement*, 96 Circulation II-286 (1997) ("Argenziano"); E. Lechner et al., *Arginine-Vasopressin in Neonates with Vasodilatory Shock After Cardiopulmonary Bypass*, 166 Eur. J. Pediatr. 1221(2007) ("Lechner"); and M.W. Dunser et al., *Cardiac Performance During Vasopressin Infusion in Postcardiotomy Shock*, 28 Intensive Care Med. 746 (2002) ("Dunser"). As also set forth in the First Notice Letter, the claims of the '478 are invalid as indefinite, pursuant to 35 U.S.C. § 112. Because one cannot infringe an invalid claim, Eagle's Proposed ANDA Product does not infringe any claim of the '478 patent for this additional reason.

27. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '478 patent. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

28. Eagle is entitled to a declaratory judgment that the submission of ANDA No. 211538 and the making, using, offering to sell, selling, and/or importing of Eagle's Proposed ANDA Product, have not, do not and will not infringe any valid and enforceable claims of the '478 Patent.

SECOND COUNTERCLAIM
Invalidity of the '478 Patent

29. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–28 of its Counterclaims as if fully set forth herein.

30. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '478 Patent.

31. The claims of the '478 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '478 are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, alone or in combination, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser.

32. In addition, as set forth in the First Notice Letter, the claims of the '478 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112.

33. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why the claims of the '478 patent are invalid. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

34. Eagle is entitled to a declaratory judgment the claims of the '478 patent are invalid.

THIRD COUNTERCLAIM
Noninfringement of the '526 Patent

35. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–34 of its Counterclaims as if fully set forth herein.

36. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the noninfringement of the '526 Patent.

37. Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '526 patent. By way of non-limiting example, as set forth in the First Notice Letter, [redacted], and therefore does not infringe any claim of the '526 patent.

38. In addition, the claims of the '526 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, each alone or in combination with one or more others, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser. As also set forth in the First Notice Letter, the claims of the '526 are invalid as indefinite, pursuant to 35 U.S.C. § 112. Because one cannot infringe an invalid claim, Eagle's Proposed ANDA Product does not infringe any claim of the '526 patent for this additional reason.

39. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for the for why Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '526 patent. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

40. Eagle is entitled to a declaratory judgment that the submission of ANDA No. 211538 and the making, using, offering to sell, selling, and/or importing of Eagle's Proposed ANDA Product have not, do not, and will not infringe any valid and enforceable claims of the '526 Patent.

FOURTH COUNTERCLAIM
Invalidity of the '526 Patent

41. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–40 of its Counterclaims as if fully set forth herein.

42. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '526 Patent.

43. The claims of the '526 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '526 are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, alone or in combination, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser.

44. In addition, as set forth in the First Notice Letter, the claims of the '526 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112.

45. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why the claims of the '526 patent are invalid. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

46. Eagle is entitled to a declaratory judgment the claims of the '526 patent are invalid.

FIFTH COUNTERCLAIM
Noninfringement of the '209 Patent

47. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–46 of its Counterclaims as if fully set forth herein.

48. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the noninfringement of the '209 Patent.

49. Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '209 patent. By way of non-limiting example, as set forth in the First Notice Letter, [redacted] and therefore does not infringe any claim of the '209 patent.

50. In addition, the claims of the '209 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, each alone or in combination with one or more others, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser. As also set forth in the First Notice Letter, the claims of the '209 are invalid as indefinite, pursuant to 35 U.S.C. § 112. Because one cannot infringe an invalid claim, Eagle's Proposed ANDA Product does not infringe any claim of the '209 patent for this additional reason.

51. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '209 patent. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

52. Eagle is entitled to a declaratory judgment that the submission of ANDA No. 211538 and the making, using, offering to sell, selling, and/or importing Eagle's Proposed ANDA Product have not, do not, and will not infringe any valid and enforceable claims of the '209 Patent.

SIXTH COUNTERCLAIM
Invalidity of the '209 Patent

53. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–52 of its Counterclaims as if fully set forth herein.

54. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '209 Patent.

55. The claims of the '209 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '209 are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, alone or in combination, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser.

56. In addition, as set forth in the First Notice Letter, the claims of the '209 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112.

57. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why the claims of the '209 patent are invalid. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

58. Eagle is entitled to a declaratory judgment the claims of the '209 patent are invalid.

SEVENTH COUNTERCLAIM
Noninfringement of the '239 Patent

59. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–58 of its Counterclaims as if fully set forth herein.

60. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the noninfringement of the '239 Patent.

61. Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '239 patent. By way of non-limiting example, as set forth in the First Notice Letter, [redacted] and therefore Eagle's Proposed ANDA product does not infringe any claim of the '239 patent.

62. In addition, the claims of the '239 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, each alone or in combination with one or more others, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser. As also set forth in the First Notice Letter, the claims of the '239 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112. Furthermore, as set forth in the First Notice Letter, the claims of the '239 patent are

invalid for lack of enablement, pursuant to 35 U.S.C. § 112. Because one cannot infringe an invalid claim, Eagle's Proposed ANDA Product does not infringe any claim of the '239 patent for this additional reason.

63. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '239 patent. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

64. Eagle is entitled to a declaratory judgment that the submission of ANDA No. 211538 and the making, using, offering to sell, selling, and/or importing of Eagle's Proposed ANDA Product have not, do not, and will not infringe any valid and enforceable claims of the '239 Patent.

EIGHTH COUNTERCLAIM
Invalidity of the '239 Patent

65. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–64 of its Counterclaims as if fully set forth herein.

66. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '239 Patent.

67. The claims of the '239 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '239 are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First

Notice Letter, alone or in combination, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser.

68. In addition, as set forth in the First Notice Letter, the claims of the '239 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112.

69. Furthermore, as set forth in the First Notice Letter, the claims of the '239 patent are invalid for lack of enablement, pursuant to 35 U.S.C. § 112.

70. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why the claims of the '239 patent are invalid. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

71. Eagle is entitled to a declaratory judgment the claims of the '239 patent are invalid.

NINTH COUNTERCLAIM
Noninfringement of the '785 Patent

72. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–71 of its Counterclaims as if fully set forth herein.

73. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the noninfringement of the '785 Patent.

74. Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '785 patent. By way of non-limiting example, as set forth in the First Notice Letter, [redacted] and therefore does not infringe any claim of the '785 patent.

75. In addition, the claims of the '785 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, each alone or in combination with one or more others, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser. As also set forth in the First Notice Letter, the claims of the '785 are also invalid as indefinite, pursuant to 35 U.S.C. § 112. Because one cannot infringe an invalid claim, Eagle's Proposed ANDA Product does not infringe any claim of the '785 patent for this additional reason.

76. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for why Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '785 patent. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

77. Eagle is entitled to a declaratory judgment that the submission of ANDA No. 211538 and the making, using, offering to sell, selling, and/or importing of Eagle's Proposed ANDA Product have not, do not, and will not infringe any valid and enforceable claims of the '785 Patent.

TENTH COUNTERCLAIM
Invalidity of the '785 Patent

78. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–77 of its Counterclaims as if fully set forth herein.

79. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '785 Patent.

80. The claims of the '785 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '785 are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the First Notice Letter, alone or in combination, including: Treschan; PPC; Fresenius Label; Pitressin Label; Argenziano; Lechner; and Dunser.

81. In addition, as set forth in the First Notice Letter, the claims of the '785 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112.

82. In accordance with 21 U.S.C. § 355(j)(2)(B), the First Notice Letter included a detailed statement of the factual and legal bases for the for why the claims of the '785 patent are invalid. Eagle incorporates by reference these factual and legal bases provided in the First Notice Letter.

83. Eagle is entitled to a declaratory judgment the claims of the '785 patent are invalid.

ELEVENTH COUNTERCLAIM
Noninfringement of the '223 Patent

84. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–83 of its Counterclaims as if fully set forth herein.

85. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the noninfringement of the '223 Patent.

86. Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '223 patent. By way of non-limiting example, as set forth in the Second Notice Letter, [redacted]

[redacted] and therefore does not infringe any claim of the '223 patent. In addition, [redacted] Eagle's Proposed ANDA product would not infringe any claim of the '223 patent for this additional reason. Further, [redacted] and therefore does not infringe any claim of the '223 patent for this additional reason.

87. Additionally, the claims of the '223 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the Second Notice Letter, each alone or in combination with one or more others, including: Treschan; PPC; Fresenius Label; Pitressin Label; Dunser; J. Russell et al., *Vasopressin Versus Norepinephrine Infusion in Patients with Septic Shock*, 358 New Eng. J. Med. 877 (2008) ("Russell"); and R. Nunez et al., *Terlipressin Continuous Infusion: Please Mind the Solvent!*, 10 Current Drug Targets 577 (2009) ("Nunez"). As also set forth in the Second Notice Letter, the claims of the '223 are invalid as indefinite, pursuant to 35 U.S.C. § 112. Because one cannot infringe an

invalid claim, Eagle's Proposed ANDA Product does not infringe any claim of the '223 patent for this additional reason.

88. In accordance with 21 U.S.C. § 355(j)(2)(B), the Second Notice Letter included a detailed statement of the factual and legal bases for why Eagle has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '223 patent. Eagle incorporates by reference these factual and legal bases provided in the Second Notice Letter.

89. Eagle is entitled to a declaratory judgment that the submission of ANDA No. 211538 and the making, using, offering to sell, selling, and/or importing of Eagle's Proposed ANDA Product have not, do not, and will not infringe any valid and enforceable claims of the '223 Patent.

TWELFTH COUNTERCLAIM
Invalidity of the '223 Patent

90. Eagle incorporates by reference and realleges the allegations set forth in Paragraphs 1–89 of its Counterclaims as if fully set forth herein.

91. There is an actual, substantial, and continuing justiciable case or controversy between Defendant/Counterclaim Plaintiff Eagle and Plaintiffs/Counterclaim Defendants Par, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '223 Patent.

92. The claims of the '223 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '223 are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in the Second Notice Letter, alone or in combination, including: Treschan; PPC; Fresenius Label; Pitressin Label; Dunser; Russell; and Nunez.

93. In addition, as set forth in the Second Notice Letter, the claims of the '223 patent are invalid as indefinite, pursuant to 35 U.S.C. § 112.

94. In accordance with 21 U.S.C. § 355(j)(2)(B), the Second Notice Letter included a detailed statement of the factual and legal bases for the for why the claims of the '223 patent are invalid. Eagle incorporates by reference these factual and legal bases provided in the Second Notice Letter.

95. Eagle is entitled to a declaratory judgment the claims of the '223 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Eagle respectfully requests that this Court enter a Judgment and Order against Par as follows:

A. Dismissing Par's Complaint with prejudice;

B. Declaring that Eagle has not and will not directly or indirectly infringe any valid claim of the '478 patent;

C. Declaring that the claims of the '478 patent are invalid;

D. Declaring that Eagle has not and will not directly or indirectly infringe any valid claim of the '526 patent;

E. Declaring that the claims of the '526 patent are invalid;

F. Declaring that Eagle has not and will not directly or indirectly infringe any valid claim of the '209 patent;

G. Declaring that the claims of the '209 patent are invalid;

H. Declaring that Eagle has not and will not directly or indirectly infringe any valid claim of the '239 patent;

I. Declaring that the claims of the '239 patent are invalid;

J. Declaring that Eagle has not and will not directly or indirectly infringe any valid claim of the '785 patent;

K. Declaring that the claims of the '785 patent are invalid;

L. Declaring that Eagle has not and will not directly or indirectly infringe any valid claim of the '223 patent;

M. Declaring that the claims of the '223 patent are invalid;

N. Awarding Eagle its costs and expenses in this action;

O. Denying Par's request for injunctive relief;

P. Declaring this case exceptional under 35 U.S.C. § 285, and awarding Eagle its attorneys' fees, costs, and expenses in this action; and

Q. Awarding Eagle such other and further relief that the Court deems just and proper.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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